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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,200	04/09/2004	David Lentz	760-129 DIV/CIP/CON II	2373

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HOFFMANN & BARON, LLP
6900 JERICHO TURNPIKE
SYOSSET, NY 11791

EXAMINER	
JACKSON, SUZETTE JAMIE	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,200	LENTZ ET AL.	
	Examiner	Art Unit	
	Suzette J Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/9/04; 7/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Therefore the priority date relied upon for 10/822,200 (the current application) will be from patent 6,428,571 filed **3/14/00** which is when "self-sealing" properties are introduce.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 29-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanzer 4,619,641 in view of Parsons et al. 6,521,284. Shanzer discloses the invention as claimed comprising: a first tubular (11) structure having a first thickness/porosity; and

a second tubular (13) structure having a second thickness/porosity wherein the tubular structure is disposed externally about the first tubular structure and a resealable layer (15) made of silicone (a polymer) which is interposed between the first and second tubular structures for the purpose chronic hemodialysis access (col. 1, lines 9-18, col. 2, line 65). While Shanzer does disclose a ***PTFE*** material (col. 2, lines 48, 51), Shanzer does not disclose the use of ***ePTFE*** or adherance or a flowable material. Parsons et al. teaches grafts (see figures 1-4) with self-sealing properties (col. 10, lines 64-67 to col. 11, lines 1-51), which utilize ePTFE (col. 9, lines 19-21); a hydrogel that contains water (which equates to the flowable gel, see col. 6, lines 30-33); and wherein the self-sealing material is disposed within a cavity such that the cross-linkable material is adjacent to layers (22) (see col. 5, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to exchange the PTFE material of Shanzer to the ePTFE (as taught by Parsons et al.) because the ePTFE exhibits a high level of porosity and biocompatibility. It also would have been obvious to create a self-sealing flowable layer that adheres to the first and second layers because the flowable gels are know to deform elastically and then recover to their original form which would aid in the production of attaching the gel to the layers of the graft.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 29, 32, 34-35, 37, 40-41, 43-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,428,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent 428,571 claims: a self-sealing graft with resealable polymer (lines 1 and 7); wherein the second tubular structure has a porosity of a less amount than the first layer (claim 1, lines 3-4); including an elastomer (claim 2,lines 2-3) which adheres to the first and second layers (claim 3, lines 2); impregnated with a gel (claims 11-12); wherein there flowable material (claim 11); and wherein there are silicones and fluoropolymers (claims 4, 13). It is obvious to one having ordinary skill in the art that the application claims are merely reworded a broader manner.

6. Claims 29-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,719,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of patent '783 claims all of the

subject matter of the current applicant along with additional features and it is obvious that the current application is reworded in a broader context.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shannon et al., 6,319,279 ; Kowligi et al. 5,466,509 ; and Sinnott 5,246,452 show related material.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

9. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Suzette J-J Gherbi
21 January 2005